

2. The scientific abstract.

Lower limb intermittent claudication (IC), muscular pain with exercise relieved promptly by rest, is a prevalent and disabling disease affecting over 10 million patients in the United States. Intermittent claudication is caused by peripheral artery atherosclerosis impairing blood flow to the lower limbs. Growth factors, such as vascular endothelial growth factor (VEGF-A), have been shown in animal studies to improve blood flow to the lower limbs by promoting the growth of new blood vessels. The primary objective of this study is to establish the safety and feasibility [of delivering] EW-A-401, a formulated plasmid encoding the transgene for a zinc finger transcription factor engineered to enhance the expression of all VEGF-A isoforms in the skeletal muscle of subjects with IC. This Phase 1 study has a randomized, double-blind, dose-escalation, placebo-controlled design. The primary outcome measure will be assessment of safety and tolerability. In addition, we will collect exploratory efficacy and biological activity data including perfusion, function, quality of life, and histopathology.